AVITA Medical Receives U.S. FDA Investigational Device Exemption Approval of Clinical Feasibility Study to Evaluate RECELL System for Vitiligo

December 29, 2019

Valencia, Calif., USA, and Melbourne, Australia, 30 December 2019 — AVITA Medical Limited (ASX: AVH, NASDAQ: RCEL), a regenerative medicine company with a technology platform positioned to address unmet medical needs in therapeutic skin restoration, announced today that the U.S. Food and Drug Administration (FDA) has approved the company's Investigational Device Exemption (IDE) application to conduct a feasibility study evaluating the safety and effectiveness of the RECELL® Autologous Cell Harvesting Device (RECELL® System) for repigmentation of depigmented lesions associated with stable vitiligo.

"Vitiligo affects approximately 6.5 million people in the United States(i), rivalling the prevalence of psoriasis(ii); however, there are limited treatment options available to patients to permanently restore skin pigmentation," said Dr. Mike Perry, AVITA Medical Chief Executive Officer. "We're pleased with the FDA's decision which allows us to begin our vitiligo study in the first half of 2020. Based on the outcomes of the feasibility study, we anticipate proceeding with a pivotal clinical trial to pursue FDA approval of the RECELL System as a cell-based repigmentation treatment option for stable vitiligo."

Vitiligo is a disease resulting in loss of color, or pigmentation, in patches of skin that impacts the quality of life for those living with the condition.(iii) There is currently no cure for vitiligo, nor a universally accepted method for limiting the spread of the disease. Although many treatments are being used for the management of vitiligo, they are often temporary with a high rate of recurrence.(iv)

"This study expands on peer-reviewed, published effectiveness outcomes to confirm the feasibility of RECELL as a treatment for repigmentation in cases of stable vitiligo," said Andy Quick, AVITA Medical's Chief Technology Officer. "Given the RECELL System's broad approval outside of the U.S., more than 1,000 vitiligo patients have already been treated globally and reported repigmentation."

AVITA Medical will collaborate with a leading medical center to conduct a pilot study with 10 patients who have vitiligo lesions that have been stable for at least one year. Areas of the vitiligo lesion will be randomly treated with slightly varying cell suspensions prepared using RECELL to confirm response rates and optimal suspension parameters.

The randomized controlled study's primary effectiveness measure is the percent area of repigmented skin 24 weeks after treatment, as evaluated by a clinician blinded to the treatment assignment.

Additional effectiveness data collected over the course of the 24-week study will include degree of repigmentation achieved and patient rating of repigmentation.

Of note: Use of the RECELL System in patients undergoing reconstruction of skin defects not associated with a burn injury is limited by Federal law to investigational use.

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ABOUT AVITA MEDICAL LIMITED

AVITA Medical is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Medical's patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. The medical devices work by preparing a RE- GENERATIVE EPIDERMAL SUSPENSION™ (RES™), an autologous suspension comprised of the patient's skin cells necessary to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

AVITA Medical's first U.S. product, the RECELL® System, was approved by the U.S. Food and Drug Admin- istration (FDA) in September 2018. The RECELL System is indicated for use in the treatment of acute thermal burns in patients 18 years and older. The RECELL System is used to prepare Spray-On Skin™ Cells using a small amount of a patient's own skin, providing a new way to treat severe burns, while signifi- cantly reducing the amount of donor skin required. The RECELL System is designed to be used at the point of care alone or in combination with autografts depending on the depth of the burn injury. Com- pelling data from randomized, controlled clinical trials conducted at major U.S. Burn Centers and real- world use in more than 8,000 patients globally, reinforce that the RECELL System is a significant ad- vancement over the current standard of care for burn patients and offers benefits in clinical outcomes and cost savings. Healthcare professionals should read the INSTRUCTIONS FOR USE - RECELL® Autolo- gous Cell Harvesting Device (https://recellsystem.com/) for a full description of indications for use and important safety information including contraindications, warnings and precautions.

In international markets, our products are marketed under the RECELL System brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics. The RECELL Sys- tem is TGA-registered in Australia and received CE-mark approval in Europe. To learn more, visit www.avitamedical.com

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This letter includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look for- ward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this letter include, but are not limited to, state- ments concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strate- gic, operational and financial goal. Forward-looking statements by their nature address matters that are, to differ- ent degrees, uncertain. Each forward- looking statement contained in this letter is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties

include, among others, the timing of regulatory approvals of our products; physician ac- ceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside

of the company's control. Investors should not place considerable reliance on the forward-looking statements con- tained in this letter. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this letter speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements. This press release was authorized by the review committee of AVITA Medical.

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PR 20191230

(i) Advances in Vitiligo: An Update on Medical and Surgical Treatments. A. Dillon, et al. J Clin Aesth Derm. 2017

(ii) National Psoriasis Foundation – Statistics, https://www.psoriasis.org/content/statistics Accessed 12/28/19

(iii) Willingness-to-pay and quality of life in patients with vitiligo. Radtke, et al. BJD. 2009

(iv) Vitiligo Research Foundation – Treatment Guidelines. https://vrfoundation.org/treatment_guidelines Accessed 12/28/19